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510(k) SUMMARY
Osteo IC Femoral and Tibial Nails in Titanium Alloy

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 201-825-4900
Contact Person:	Marybeth Naughton Regulatory Affairs Specialist
Date Summary Prepared:	June 15, 1999

Device Identification

Proprietary Name:	Osteo IC Femoral and Tibial Nails in Titanium Alloy
Common Name:	Intramedullary Nail, Tibial Nail
Classification Name and Reference:	Intramedullary Fixation Rod 21 CFR §888.3020

Predicate Device Identification

The subject Osteo IC Femoral and Tibial Nails in Titanium Alloy are compared to the following predicate devices:

- Osteo IC Femoral and Tibial Nails in Stainless Steel
- Howmedica Alta Femoral and Tibial Rod System in Titanium Alloy

Device Description

The subject Osteo IC Femoral and Tibial Nails are similar to the predicate Osteo IC Femoral and Tibial Nails. The major difference is that the subject devices are made from Titanium Alloy, while the predicate devices were made from Stainless Steel.

Intended Use

The intended uses of the subject Osteo IC Femoral and Tibial Nails are the same as those of the predicate Osteo IC Femoral and Tibial Nails. The nails are single use devices. They are intended for the fixation, correction, or stabilization of tibial and femoral bones. The nails may be locked statically, dynamically, or with active primary compression. The indications for use of the subject

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Osteo IC Femoral and Tibial Nails are the same as those of the predicate Osteo IC Femoral and Tibial Nails:

- Closed and open femoral and tibial shaft fractures
- Pseudarthrosis and correction osteotomies in the shaft area
- Pathological fractures and tumor resections of the shaft area
- Change of procedure following external fixation

Statement of Technological Comparison

The subject Osteo IC Femoral and Tibial Nails in Titanium share the same basic design as the Osteo IC Femoral and Tibial Nails in Stainless Steel, except that they feature an additional groove and come in some additional sizes. The predicate Howmedica Alta Nails, presented as one of the comparison devices for substantial equivalence, are manufactured from Titanium and come in a wider range of sizes than presented for the subject devices.

Performance Data:

The subject devices are so similar to the predicate devices cited in terms of design, materials, intended use, and size range, that additional testing was not thought necessary to demonstrate their Substantial Equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 1999

Ms. Elizabeth A. Staub
Director, Quality Assurance & Regulatory Affairs
Stryker® Howmedica Osteonics
59 Route 17
Allendale, New Jersey 07401-1677

Re: K992063
Trade Name: Osteo IC Femoral and Tibial Nails in Titanium Alloy
Regulatory Class: II
Product Code: HSB
Dated: June 15, 1999
Received: June 18, 1999

Dear Ms. Staub:

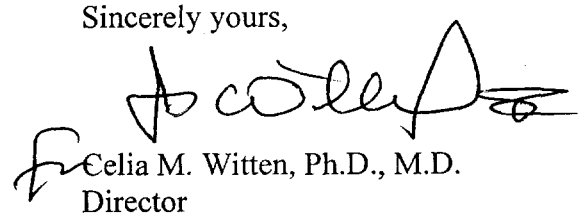
We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General Regulation (21 CFR Part 820), and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K___

Device Name: Osteo IC Femoral and Tibial Nails in Titanium Alloy

Indications For Use:

The indications for the use of the Osteo IC Femoral and Tibial Nails in Titanium Alloy are as follows:

- Closed and open femoral and tibial shaft fractures
- Pseudarthrosis and correction osteotomies in the shaft area
- Pathological fractures and tumor resections of the shaft area
- Change of procedure following external fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992063

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)